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**Medical News & Perspectives**

# IDSA: Better, Faster Diagnostics for Infectious Diseases Needed to Curb Overtreatment, Antibiotic Resistance

Bridget M. Kuehn, MSJ

It can take several hours or even days to get results of diagnostic tests that might provide key information about the potential cause of a patient's infection. But in many cases, waiting that long to initiate treatment would be unwise or impractical, so physicians often begin to do so based on an educated guess.

This practice has been linked to overtreatment and the emergence of antimicrobial resistance. For example, about half of patients with respiratory infections receive antibiotics, although many such infections are caused by viruses. This leads to unnecessary exposure to antibiotics that will not help the patient, may cause adverse events, and may contribute to the emergence of antibiotic-resistant bacteria.

To curb such empirical use, a report from the Infectious Diseases Society of America (IDSA) is calling for steps to boost the development of better diagnostic tests, to reduce regulatory hurdles for new tests, and to improve clinical use of infectious disease diagnostics (Caliendo AM et al. *Clin Infect Dis*. 2013;57[S3]:S139-S170).

"With the current state of diagnostic testing, we are handicapped, making decisions based on limited or nonspecific information—in situations ranging from helping individual patients to identifying broader public health threats," said Angela M. Caliendo, MD, PhD, lead author of the report and executive vice chairman of the Department of Medicine at the Warren Alpert Medical School of Brown University, Providence, RI, in a statement.

**Faster Development, Smarter Use**

Caliendo and her colleagues emphasized the need for simple and inexpensive diagnostics that are rapid, often providing results within an hour.

Diagnostic delays can lead to patient harm and additional unnecessary tests and can drive up the cost of care, noted Daniel J. Diekema, MD, director of the divi-

sion of infectious diseases at the University of Iowa Carver College of Medicine in Iowa City. For example, it may take days to get results determining the infectious cause of encephalitis. Because there are risks associated with waiting to begin treatment, physicians may try many possible options until the results come back.

**SAVE LIVES**

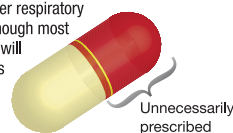
Better tests can speed the diagnosis of sepsis, a severe and sometimes fatal response to infection. Currently, 20-30% of patients receive inadequate antibiotic therapy for the condition—often leading to death—because it can take 1-5 days to diagnose.<sup>1</sup>

**REDUCE SIDE EFFECTS**

Rates of *Clostridium difficile*, an infection caused by inappropriate antibiotic use, rose 200% from 1996 to 2009.<sup>2</sup> With improved diagnostics, doctors would be better able to target antibiotics to specific infections, potentially reducing the existence of the disease.

**CURB RESISTANCE**

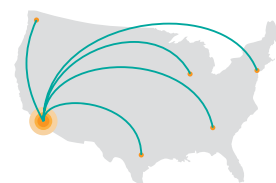
50% or more of people with upper respiratory infections receive antibiotics although most do not need them.<sup>1</sup> Better tests will help doctors prescribe antibiotics only when necessary.

**DETECT INFECTION**

62% of patients with encephalitis— inflammation of the brain often caused by viral infection—remain undiagnosed.<sup>1</sup> New tests for central nervous system infections are desperately needed.

**LIMIT THE SPREAD**

Improved diagnostics could more quickly identify the cause of food-borne illnesses, which currently takes days to weeks.<sup>1</sup>

**CUT COSTS**

Rapid testing for methicillin-resistant *Staphylococcus aureus* (MRSA) has been shown to save \$21,387 per patient.<sup>1</sup> Integration of successful testing protocols into care may be able to reduce the financial burden of healthcare.



<sup>1</sup> IDSA, "Better Tests, Better Care: Improved Diagnostics for Infectious Diseases"

<sup>2</sup> CDC, "Rates of *Clostridium difficile* Infection Among Hospitalized Patients Aged ≥65 Years"

Improvements in diagnostic tests that reduce delays in getting test results have the potential to save lives and curb health costs, according to a report from the Infectious Diseases Society of America.

"It really helps to find out sooner and to narrow therapy," said Diekema, who was not involved in drafting the IDSA report.

The report argues that improved diagnostics are also needed to aid public health efforts, such as rapidly identifying the cause of outbreaks, determining whether an infectious agent is resistant to first-line antimicrobials, and curbing the emergence of drug resistance by encouraging more judicious use of antimicrobials.

Caliendo explained in a press briefing, however, that despite demand for such diagnostics there is often little incentive for companies to develop and market them. For example, it may cost a company millions to develop a test that will only be used in a small market. In such cases, recouping these costs may take years and some companies may never do so, she said.

The report calls for tax credits to help defray the development costs for companies and for more federal funding of research to develop new diagnostics, especially through the Small Business Innovation Research program. The report also urges the US Food and Drug Administration and other regulatory agencies to reduce regulatory hurdles to infectious disease diagnostic development and approval.

Another barrier to diagnostic development outlined in the report is a lack of ac-

cess to patient specimens for diagnostic research. The report recommends the creation of a biorepository or other system to facilitate the collection of deidentified samples from patients.

### Better Point-of-Care Use

The report also calls for measures to improve the use of diagnostic tests in clinical settings.

Caliendo said that to ensure the tests are clinically useful and cost-effective, more funding should be allocated by the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Patient Centered Outcomes Research Institute for studies on how diagnostic tests affect patient outcomes. Additionally, she said, "we want to eliminate the use of tests that aren't helpful."

The report also recommends that health care facilities develop systems to ensure use of appropriate diagnostics and rapid delivery of results to clinicians. Additionally, the Centers for Medicare & Medicaid Services should harmonize its Clinical Laboratory Improvement Amendments regulations with guidelines from such groups as the College of American Pathologists and the Clinical and Laboratory Standards Institute, the report said, to make it easier to disseminate new diagnostics in the clinical setting

and ensure that they are being used in settings with the appropriate levels of expertise.

Diekema said it is critical for health care facilities to have good systems for communicating and using diagnostic results.

"You can develop the perfect diagnostic [test], but it will only improve care if there is a system in place to make the results available quickly, and make sure they are acted on by the care team," he said.

Finally, the report advises more training for clinicians on the use of infectious disease diagnostics. Caliendo explained that it is difficult for clinicians to stay up to date on which tests are available and accurate and to know how to interpret results. "It's hard to be at the cutting edge of diagnostics and hard to know which tests will have a positive impact on care," she said.

She said that professional societies can play an important role in trying to help clinicians stay up to speed on diagnostics, and that infectious disease specialists are "sophisticated consumers" of diagnostic tests and can play a key role in advising clinicians and facilities.

"Infectious disease specialists have a key role to play in ensuring appropriate interpretation and use of diagnostic test results, particularly as tests become more complex," she said. ■

## FDA Moves to Further Reduce Trans Fat in Food

Bridget M. Kuehn, MSJ

**A** man-made fat that helped propel margarine into place as a household staple is being targeted by the US Food and Drug Administration (FDA) as an unsafe food ingredient.

Trans fats, or partially hydrogenated fats, which naturally occur in foods in small amounts, emerged on the food manufacturing scene in the early 20th century, according to the American Heart Association (<http://bit.ly/f3P9Tm>). Over time, manufactured trans fats became common ingredients in products such as margarine and shortening. During the mid-1980s, a push to reduce the use of saturated fats, which were known to contribute

to heart disease, led many restaurants to replace saturated fats from beef tallow or plant oils with trans fats. The move was driven by the belief that these fats were less problematic than saturated fats.

But by the 1990s, evidence emerged that trans fats elevate the risk of heart disease by increasing harmful low-density lipoprotein cholesterol and lowering beneficial high-density lipoprotein cholesterol levels. In 1993, the Center for Science in the Public Interest asked the FDA to require that food labels list trans fats, and in 2003 the agency did so. Many food manufacturers responded by reducing or

eliminating trans fats from their products, but a few products such as microwave popcorn and artificial creamers still contain trans fats, according to the FDA.

As food producers have steered away from trans fats, the annual number of deaths related to consumption of these products has decreased from about 50 000 to 7000 or fewer, according to the center. However, the FDA would like to reduce these levels even further by revoking the "generally recognized as safe" designation for trans fats, which would require more manufacturers to remove these ingredients from their products. ■